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LEYDIG VOIT & MAYER, LTD
TWO PRUDENTIAL PLAZA, SUITE 4900
180 NORTH STETSON AVENUE
CHICAGO, IL 60601-6780

EXAMINER

YU, GINA C

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/851,882
Filing Date: May 09, 2001
Appellant(s): GHOSH ET AL.

KENNETH SPINA
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed on August 2, 2005 appealing from the Office action mailed on February 9, 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,889,062	HOPPE ET AL.	03-1999
4,654,373	BERTELLI	03-1987

Eucerin press release "Eucerin Pressemitteilungen, October, 2000. Beiersdorf, AG.

Eucerin Q10 Anti-Wrinkle product package.

"Q-Pharma, Inc. Grants Non-Exclusive CoQ10 License to Beiersdorf AG", Business Wire, February 1, 1999, p. 1, abstract.

FDC Reports, October 26, 1992, Vol. 13, No. 43.

Raab, W., "Uses of Urea in Cosmetology", May 1990, Cosmetics & Toiletries, Vol. 105, Allured Publishing Corp., p. 97-102.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

A. Claims 1-13, 17-29, and 32-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoppe et al. (US 5889062) in view of Raab (Uses of Urea in Cosmetology, 1990).

Hoppe teaches composition comprising ubiquinones for treating senile xerosis, of which the symptoms include dryness, cracking, and roughness skin by providing moisture to the skin. See col. 1, line 9 – col. 2, line 37. The reference teaches preferably using 0.2-0.4 by weight of coenzyme Q10. See col. 3, lines 4 – 15. The reference also teaches that the active compound can be present in the topical formulations in amounts of 0.001-50 % by weight of the formulations. See col. 3, lines 39 – 48. See instant claims 47-54 and 56-68. The composition is formulated in W/O or

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O/W emulsion gel, lotion, or cream. See col. 3, lines 16 – 20; col. 4, lines 53- 60. The additives including emulsifiers, preservatives, buffer substances, thickeners, fragrances, antioxidants, vitamins, and UV protection filters are also to be added in the composition. See col. 3, line 21 – col. 4, line 48. See Examples III-V for the amount. The reference teaches using 0.1-10 wt % of the UV protection filters. See col. 4, lines 36 – 46.

Hoppe fails to teach adding urea.

Raab teaches the use of urea in concentrations of 4-10 wt % in cosmetic and/or dermatological compositions to provide moisturizing, desquamating, antimicrobial, and anti-inflammatory action to the skin. See p. 97, col. 2 – p. 98, col. 1. See instant claims 43-46 and 55. The reference teaches urea increases the therapeutic activity of other pharmaceutical substances, and in Table 3 shows the use of urea in combination with anti-inflammatory agents (glucocorticoids), tretinoin or others in the weight ratio of 10: 0.3 to 10: 5. See p. 101, first column; see instant claims 25-27. The reference recommends formulating urea-containing compositions in the form of emulsion lotion or cream, meeting instant claims 2, 3, and 38. See p. 102, col. 2.

It is generally considered prima facie obvious to combine two compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. See In re Kerkhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980). As shown by the recited teachings, the instant claims define nothing more than the concomitant use of two skin

care actives conventionally used for dry skin treatment. It would follow that the recited claims define prima facie obvious subject matter.

It would have been further obvious to one having ordinary skill in the art at the time the invention was made to have modified the Hoppe invention by adding urea as motivated by Raab because of an expectation of successfully producing a topical composition for treating skin disorders including senile xerosis, with enhanced moisturizing property and improved pharmaceutical effects of other skin care actives.

B. Claims 1-12, 14, 15, 17, 19, 20, 21, 23, 24, 29, 30, 34, 35, 38, 39, 40, 41, 43-46, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eucerin Q10 Anti-Wrinkle product package and English translation of Eucerin press release (Eucerin Pressemitteilungen, Oct. 2000) in view of Business Wire (Feb. 1, 1999), Bertelli (US 4654373) and FDC Reports (October 26, 1992).

Eucerin product packages indicates that the composition comprises water, coenzyme Q10, glycerin (moisturizer), hydrogenated coco-glycerides (solid emollient), caprylic/capric triglyceride (oil), biosaccharide gum-1 (thickener), carbomer (thickener), parabens (preservatives), titanium dioxide (sunscreen), and sodium hydroxide (base neutralizer), and tocopheryl acetate (vitamin E, an antioxidant). See instant claims 1-12, 14, 15, 17, 19, 20, 21, 23-27, 29, 30, 34, 35, 38, 39, 40, and 41.

Eucerin press release teaches that the product has been available in the market since October 2000 by Beiersdorf.

Eucerin product package and press release fail to neither disclose the amount of coenzyme Q10 nor teach adding urea in the composition.

Business Wire teaches that it is well known in the art that Beiersdorf uses Q-Pharma's coenzyme Q10 platform technology, which is described in Bertelli (US 4654373), in topical use non-prescription products. See Full Text.

Bertelli teaches the method of formulating and topically applying pharmaceutical or cosmethological pastes, creams, ointments, gels, lotions, or unguents which comprises 0.1-10 % Coenzyme Q10 to treat damaged and impaired skin tissue. See col. 2, lines 28 – 64.

While the Bertelli reference further suggests adding other topical actives in the composition, see col. 2, lines 61 – 64, the combined references above fail to teach adding urea in the Eucerin composition.

FDC Reports teaches that Beiersdorf produces a dry skin treatment composition comprising 5 % of urea under the tradename Eucerin Plus. See p. 14, 1st par. – 4th par. The reference teaches that the product "induces significant improvements in skin dryness and appearance relative to an untreated control". See Id.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Eucerin anti-wrinkle treatment composition by adding 5 % of urea as motivated by Bertelli and FDC Reports, because of an expectation of successfully producing an enhanced skin treatment composition which moisturizes and treats damaged and impaired skin. The motivation to use coenzyme Q10 in the weight amount of 0.1-10 % by weight of the total composition is found in the combined teachings of Beiersdorf press release, Business Wire, and Bertelli. The

claimed methods in claims 43-46 and 54 of providing moisturizing property to the skin are viewed obvious uses of the prior art cosmetic compositions.

C. Claims 13, 16, 18, 22, 28, 31, 32, 33, 36, 42, 47-53, and 55-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eucerin product package, Eucerin press release, Business Wire, Bertelli, and FDC Reports as applied to claims 1-12, 14, 15, 17, 19, 20, 21, 26, 27, 29, 30, 34, 35, 38, 39, 40, 41, 43-46, and 54 as above, and further in view of Hoppe.

The combined references fail to teach the amount of the additives and auxiliary ingredients.

Hoppe, discussed above, teaches emulsion formulations comprising coenzyme Q10 and additives. The reference also teaches incorporating coenzyme Q10 in topical formulations in the claimed amounts of instant claims 47-54 and 56-68.

Given the teaching the additives and auxiliary ingredients used in the Eucerin formulations as shown in the combined references, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have looked to the prior art such as Hoppe for the amounts of these additives in topical formulations. Furthermore, differences in concentration generally will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. See MPEP § 2144.05. Since the general conditions of the instant claims are disclosed in the combined references, examiner views that one having ordinary skill in the art would have discovered the optimum or workable ranges by routine experimentation to formulate a topically applicable, stable composition.

D. Claims 23-25 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eucerin product package, Eucerin press release, Business Wire, Bertelli, FDC Reports, and Hoppe as applied to claims 1-22, 26-36, 38-45 as above, and further in view of Raab.

While Eucerin product package teaches that the composition is designed for sensitive skin crème, the combined references above fail to teach adding soothing agents.

Raab, discussed above, teaches urea formulations comprising anti-inflammatory agents (glucocorticoids) in the weight ratio of 10: 0.3 to 10: 5. See p. 101, first column; see instant claims 25-27.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the composition of the combined references by adding soothing agents such as glucocorticoids as motivated by Raab because of an expectation of successfully producing a topical composition effective to treat irritated skin.

(10) Response to Argument

Examiner respectfully notes that the rejections are maintained in this case, as the teachings of the prior arts render the claimed invention of coenzyme Q10 and urea in the recited amount prima facie obvious, and the Rule 132 declaration submitted on April 19, 2003 does not show unexpected or surprising results but accumulated effects of two well-known skin moisturizing agents.

A. Claims are properly rejected under 35 U.S.C. § 103 (a) as the claimed inventions are prima facie obvious in view of the combined teachings of the references.

Firstly examiner notes that generally the appellants' arguments here are made against the references individually. It is well settled in patent law that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In this case, appellants generally argue that each of the cited references fail to teach the claimed composition of coenzyme Q10 and urea in a ratio of about 6:1 to about 10:1. However, none of the arguments seem to address the specific reasoning and motivations that examiner had cited from the references in the rejections.

Appellants' assertion that "the final rejection has not produced any credible evidence" to make the present invention is unpersuasive. As already indicated in the rejection, examiner respectfully points out that Hoppe teaches the moisturizing properties of ubiquinones (e.g., coenzyme Q10) and Raab teaches the moisturizing effect of urea. Coenzyme Q10 is particularly mentioned in Hoppe. Thus the references establish that both coenzyme Q10 and urea are well known active ingredients for dry skin treatment.

The combined teachings of the references render a reasonable expectation of successfully making a topical composition with moisturizing effects because 1) both Hoppe and Raab teach to make formulations in the form of emulsion, lotion, or cream;

and 2) the references teach the claimed weight amount and ratio of the two active ingredients. Hoppe teaches using 0.2-4 % by weight of coenzyme Q10, while Raab teaches using urea in concentration 4-10 % by weight. The claimed weight ratio of urea to coenzyme Q10, 6:1-10:1 is met by combining the two active ingredients as taught by the references.

As for the obviousness rejection made in view of Eucerin Q10 Anti-Wrinkle product package, Eucerin press release, Business Wire, Bertelli, and FDC reports, applicants point out the deficiencies of the each reference but is silent as to why it would have been nonobvious to combine coenzyme Q10 and urea in view of these references. The collective teachings of EucerinQ10 Anti-Wrinkle product package, Eucerin press release, Business Wire, and Bertelli teach that a composition comprising coenzyme Q10 has been available in the market. Appellants' assertion that combining FDC reports is not a "proper legal standard obviousness" is unpersuasive. FDC reports also teaches that the same company which produces Eucerin Q10 Anti-Wrinkle product also produces a dry skin treatment composition under the same tradename comprising urea, wherein urea is the active ingredient used in 5 % of a topical composition. It would have been obvious to a skilled artisan that the combination of the two ingredients would produce a dry skin treatment composition.

Appellants also argue that the fact that the rejection used multiple references is "untenable and even self-contradictory". In response to applicant's argument that the examiner has combined an excessive number of references, reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of

the claimed invention. See In re Gorman, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991).

Appellants also argue that the examiner admission that Bertelli fails to teach adding urea contradicts the statement in the final rejection that a skilled artisan would have been motivated by both Bertelli and FDC report. The statement in the final rejection merely indicates that the motivation to make the present invention stems from the combined teachings of the references.

Appellants also argue that the Business Wire suggests using the coenzyme Q10 only in non-prescription product, while FDC reports suggests that Beiersdorf's 5 % urea composition is a prescription drug, since it is distributed to doctors. Examiner asserts that these facts alone do not establish that combining the coenzyme Q10 and urea would have been nonobvious. The sole fact that certain drug is distributed to doctors does not indicate that the product is a prescriptive drug, as doctors frequently recommend over-the-counter products. Furthermore, the Business Wire article teaches that the license is non-exclusive, thus it's not only Beiersdorf who could have come up with combining coenzyme Q10 with urea.

Examiner also assert that the improvement of after-feel or reducing the rate of escape of water from the epidermis is within the scope of the enhanced moisturizing effects that are expected from combining the teachings of the references.

B. Declaration under 37 C.F.R. § 1.132 does not overcome the prima facie case of obviousness in this case, as there is no evidence of unexpected or surprising results.

Appellants seek to establish that the combining urea and coenzyme Q10 in claimed weight ratio and weight amount produces greater than expected moisturizing effects by measuring the "moisturisation value" of the skin of five panelists, using a Nova DPM 9003 meter. According to the comparison graph, at hour 3, coenzyme Q10 alone is said to achieve about 12 % while urea alone achieves 11 % of the "moisturisation value". The declaration indicates that a composition comprising 0.3 % of urea and 0.05 % of coenzyme Q10 produces about 23.5 % of moisturisation value, which is viewed as a cumulative and thus expected effect of the two moisturizing active ingredients.

At hour 4, coenzyme Q10 and urea still produce about 7.5 % and 10.5 % of the moisturisation value, while the combined composition produces about 26 % (additive value \approx 18%). Examiner is mindful that unexpected results can be shown by the evidence of synergistic effects. However, a greater than additive effect is not necessarily sufficient to overcome a prima facie case of obviousness because such an effect can either be expected or unexpected. See MPEP § 716.02(a)(I). Applicants must further show that the results were greater than those which would have been expected from the prior art to an unobvious extent, and that the results are of a significant, practical advantage. See Ex parte The NutraSweet Co., 19 USPQ2d 1586 (Bd. Pat. App. & Inter. 1991) (Evidence showing greater than additive sweetness resulting from the claimed mixture of saccharin and L-aspartyl-L-phenylalanine was not sufficient to outweigh the evidence of obviousness because the teachings of the prior art lead to a general expectation of greater than additive sweetening effects when using

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mixtures of synthetic sweeteners.). In this case, Raab teaches to use urea in cosmetic compositions not only for moisturizing action, but also for "enhancement of the penetration and/or activity of other drugs". See 98. The reference also teaches the significant increase of moisturizing activity of urea when added to the glycerol/water control. See p.98, second col. – p. 100, first col.; p. 99., Figures 3 and 4. Thus enhanced activity of other drugs, such as coenzyme Q10 in this case, is generally expected, and the data showing the moisturizing value of the two components is not sufficient to overcome the evidence of obviousness.

For the above reasons, it is believed that the rejections should be sustained.


Respectfully submitted,


Gina Yu

Conferees:

THURMAN K. PAGE, M.A., J.D.
SUPERVISORY PATENT EXAMINER




GREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER